

CRIB BUMPERS MEETING

MARYLAND DEPARTMENT OF HEALTH AND MENTAL HYGIENE

201 West Preston Street
Lobby Room 2
Baltimore, Maryland 21201

Wednesday, July, 13, 2011, 2:00 p.m.- 4:00 p.m.

ATTENDANCE:

Dr. Patricia Aronica-Pollak, Office of Chief Medical Examiner

Dr. Joshua Sharfstein, Secretary, Department of Health and Mental Hygiene

Dr. Marsha Smith, Department of Health & Mental Hygiene

PANEL:

Dr. Peter Beilenson, Health Officer, Howard County Health Department

Dr. Tina L. Cheng, Professor of pediatrics and public Health, Johns Hopkins School of Medicine

Dr. Gaurov Dayal, Chief Medical Officer, Adventist Healthcare

Dr. Joseph Wiley, Chairman of Pediatrics, Children's Hospital at Sinai

Transcribed by Regina Channell in association with
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Glen Burnie, Maryland

P R O C E E D I N G S

DR. SMITH: I'm Dr. Marsha Smith. And we're going to start the meeting crib bumper panel.

I'd first like to welcome everybody for attending today. I'm Marsha Smith, Director of Perinatal and Reproductive Health with the Center for Maternal and Child Health.

As a Department, we're joined today -- the Secretary and I are joined today by Dr. Patricia Aronica-Pollak from the Office of the Chief Medical Examiner.

As you know, the panel met on May 20th to review the use of crib bumper pads in infant cribs. And the panel provided some recommendations to the Department.

This is a follow-up meeting. Part of this meeting will include a presentation by the Juvenile Products Manufacturers Association.

We ask that the panel hear the information

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that is presented. You had -- you received the documents in advance. And after hearing this presentation and considering the information as presented, we ask if this has a change in your recommendations that were already presented.

I would like everyone to turn on your microphone. I want to remind everyone as before, this meeting is being recorded and transcripts will be made available after the meeting and posted on our website.

Before we begin, I'd like everyone to review their packets. In front of you today, you have today's agenda. Behind the agenda, which is blue, there's the conflict of interest disclosure statement.

I'm not going to read the questions each time in front of each panel member. I want to just read them once and before you introduce your -- or after you introduce yourself, I'd like you to indicate if you have any conflict of interest. Okay?

So the conflict of interest disclosure

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questions are: Do you or any immediate family member have an ownership interest in any organization or commercial entity with a direct interest in the matters you will be discussing today?

Are you or an immediate family member employed by an organization or commercial entity with a direct interest in the matters that you will be discussing today?

Are you aware of any reason why you would not participate impartially in any -- in today's discussion?

So I'd like to begin with the panel introductions and then we'll introduce the Secretary. So if you would begin.

DR. WILEY: Sure. So I'm Joe Wiley. I am the Chairman of the Department of Pediatrics at the Children's Hospital at Sinai.

And I have no conflicts of interest to any of the three questions.

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DR. SMITH: Thank you.

DR. DAYAL: Gaurov Dayal. I'm the Chief Medical Officer for Adventist Healthcare based in Rockville, Maryland.

And I also have no conflicts of interest.

DR. SMITH: Thank you.

DR. CHENG: I'm Tina Cheng. I'm a Medical Professor of Pediatrics at Johns Hopkins University.

And I have no conflicts of interest.

DR. BEILENSEN: I'm Peter Beilenson, Howard County Health Officer.

No conflicts of interest.

DR. SMITH: Thank you.

It's recognized that the panel members are participating as experts in the area of pediatrics and public health. And they have no -- their organizations that they are employed by are not -- they're not representing their organizations today.

I'd like to introduce the Secretary of the

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Department, Dr. Sharfstein.

DR. SHARFSTEIN: Great. Thank you.

Thanks to you all again for coming for the second time and helping us think through this issue.

Subsequent to the first meeting, we received some information from the Juvenile Products Manufacturers Association and a request for them to be able to make a presentation. And given that it hadn't been prepared by the first meeting, we figured that it was a good opportunity to get some further analysis and input.

I have asked Dr. Beilenson again to kind of be the leader in terms of kind of directing traffic. I think the plan is for sort of three sections of the meeting, presentation, questions, and then a discussion amongst you all.

And, again, I, you know, I think that we're trying to think this through and figure out what the right thing to do is and we really value the time that

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you're spending on this, I realize how busy all of you are, and your input.

So with that, why don't we get going.

I'm also pleased that we're joined by one of the Assistant Medical Examiners from the -- who works at the Department of Health and Mental Hygiene and she has some -- obviously more than some attention (phonetic) pathological expertise. And since some of those issues are here and there's some expertise in the department, we asked her to sit in and contribute from the Department's side.

Any questions for us from the panel at this point?

VOICE: (Indiscernible) ask questions as part of the discussion right after the presentation?

DR. SHARFSTEIN: Yeah. I think --

DR. SMITH: That's right.

DR. SHARFSTEIN: Yeah, yeah. She may ask questions of the JPMA and also be available to answer

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questions from you all.

DR. SMITH: Okay.

DR. SHARFSTEIN: So anything?

DR. SMITH: All right. You have before you the information that was sent by JPMA, their letter and the two documents, the Consumer Product Safety Commission White Paper and the accident study.

So you've had a chance to review those and I believe the Juvenile Products Manufacturers Association should have five individuals who would like to present.

I'd ask you to come to the table. All right. And I'm going to ask after you introduce yourselves for the record, give your name and your title, I'm going to turn it over to Dr. Beilenson. Okay?

MR. ENTEN: Thank you very much.

My name is Robert Enten. I'm an attorney. I know several of you. I'm with the Gordon, Feinblatt

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Law Firm in Baltimore City. I'm here today representing Juvenile Products Manufacturers Association.

MR. LOCKER: Yes. My name is Rick Locker, Frederick Locker. I am also an attorney by trade. I am independent general counsel to the Juvenile Products Manufacturers Association and a number of other groups with an expertise in (indiscernible).

MS. PFEIFFER: Hi. My name is Lauren Pfeiffer and I'm the Assistant Executive Director of Juvenile Products Manufacturers Association.

DR. PRANGE: My name is Michael Prange. I'm the Managing Engineer in the Biomechanics Practice of -- at Exponent.

DR. SALA: My name is Joseph Sala. I am a scientist with the firm Exponent.

DR. BEILENSEN: Thank you very much.

VOICE: (Indiscernible.)

DR. SHARFSTEIN: Yeah. We talked about --

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20 minutes we talked about?

DR. SMITH: Uh-huh.

DR. BEILENSON: And we'll also have our panel just listen to them, see if anybody has questions and we'll have some more specific question time to discuss with them. Then we'll take a third component of this. They'll step back. We'll have a discussion.

Go ahead.

MR. ENTEN: Thank you very much.

I want to start out by thanking all of you and thanking Dr. Sharfstein and Dr. Smith for letting us come today. As you can imagine, this is an extremely important issue for the manufacturers of juvenile products.

The -- unfortunately, we did not realize that the meeting was being held in May. Otherwise, we'd have come to the meeting in May. And your willingness to reschedule to hear us out today is

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very, very much appreciated.

Lauren will talk some about the Juvenile Products Manufacturers Association.

Rick is probably, I think, the foremost expert attorney in the country, private practice in child product safety issues and attends a number of trade associations including the (Indiscernible) Association and others (indiscernible) safety issues.

Then we have the two scientists here from Exponent. You have a copy of Exponent's study that was done. It was done to go back and look at the facts and try to, because (indiscernible) do not have much of the backup data that he used to try to recreate -- to recreate through the records that he looked at some of the study and the findings that he made.

I just want to start out by saying that we would very, very much hope that as you look at this issue and hear us out today that you reconsider your

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recommendation that Maryland be the only state in the country, the only -- that this department be the only regulatory body in the country or in the world, frankly, to ban the sale of bumper pads.

We are totally committed to the safety of products that our members manufacture. We do not believe that there is a justification for the total ban of bumper pads.

Further, as you will hear and we'll point to some of the materials that you've already looked at, and I think it's Dr. Cheng and Beilenson had read the transcript five times at the May meeting, and we think an unintended consequence of the ban on bumper pads will be an increase in the use of blankets, padding, comforters, and other products that clearly and unequivocally pose the most serious threat to infants in cribs.

Just to point out a couple of statements and issues from materials which I got frankly from the

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website and that is that, for instance, the Journal of Pediatrics, which is part of the materials on your website, states in an article from 2007, and I quote, "Thus it is no surprise that parents are unable to resist providing a soft environment that will protect their vulnerable infant's head and body from bumping up against the hard dangers of wooden crib slats." This is from the Journal of Pediatrics.

My point is that when you read -- carefully read through the articles and studies that have been done, they point out the fact that the use of bumper pads, and you said it in your discussion back in May and it's in the transcript, that one of the concerns that pediatricians that I think Dr. Cheng had talked to is that the perception of the public is so widespread that bumper pads protect infants, that bumper pads are no longer in the crib.

The unintended consequence would be the dangerous -- clearly dangerous materials will be

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placed in a crib that would cause a spike and an increase in suffocation. That's our concern. And we urge you before you take this step to make sure that there is a sound scientific basis for taking this step.

And I would also call your attention to the official journal, the American Academy of Pediatrics, an article from February 2011, which is a 10 or 15 page study of this issue, and nowhere is there a recommendation that the sale of bumper pads be banned.

In fact, in all the reading that I've done in preparation for today, I have yet to read any document from any regulatory body or anyone who's done a study that says the sale of bumper pads should be banned. There are recommendations that bumper pads not be used, but no one has taken that next step and said that bumper pads should be banned.

Dr. Levey from Kennedy Krieger sent an e-mail to the Advisory Committee in which he said on a

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practical basis, we would recommend avoiding the use of bumper pads for infants less than six months of age.

He says the decision to use bumper pads for older infants and toddlers should be made on a case-by-case basis when risk of injury from physical activity or falls from a crib versus risk of entrapment (indiscernible) due to the bumper pads.

In the inpatient unit at Kennedy Krieger, we use bumper pads. So I guess my point is, and I'm going to turn it over to our experts and Lauren, is that this is not an issue that has come up, upon which no study has been done. This is not an issue that's come up where federal regulators and scientists have not studied the issue. It is being studied. It's being studied today. The ASTM is -- we are participating in a study today as to what we've done to improve safety.

Crib structure has changed. Bumper pads

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have changed. Ties are shorter. The materials are firmer. But to take this leap which no one has seen fit to take and which no one, quite frankly, from any of my reading has recommended to have an outright ban we think is just not the way to go and it will have unintended consequences.

As far as I know, the Department of Health and Mental Hygiene today does not declare any material to be hazardous through its regulations and ban their sale. It is a major step to do that.

We would like to work with you to come up with education programs that would educate consumers and parents about safe sleep. We would like to work with you, if you think that we do need to regulate this area, to come up with a set of regulations that don't get out ahead of the science, but would make a positive difference and not have the perhaps unintended consequence of exposing more risk.

And with that, I'll turn it over to Lauren.

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Thank you.

MS. PFEIFFER: Thank you, Bob.

I'd like to echo Bob's point and also thank you again for taking the time to meet with us here today.

JPMA is a national trade organization and we represent 95 percent of the prenatal to preschool (indiscernible). We have about 250 member companies that we represent in the United States and Canada and Mexico who manufacture and distribute products, cribs, car seats, strollers.

JPMA works very closely with an organization that Bob referenced, the ASTM International, that's The American Society of Testing Materials. They are a standard setting organization and there are a number of ASTM subcommittees in our industry that cover all sorts of product categories that I mentioned, cribs and high chairs and strollers.

And each of these subcommittees is made up

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of manufacturers, retailers, other industry members such as testing labs, consumer advocacy groups, and the staff from the U.S. Consumer Product Safety Commission and Health Canada.

There is a standard for infant bedding and related accessories through ASTM and that standard includes different types of methods. Bob mentioned something about the length of ties, the bumper ties. That is something that is an ASTM standard. The standard also includes warnings.

And through the standard setting process, there are task groups that work with various issues and bring them to the subcommittee to build on to be incorporated into the standard.

At this time, the task group is working on additional warnings to the standard. One of the things they're looking to do is include pictograms to show what proper bumper use is, you know, if it's up against the crib slats and it's tied correctly, that

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it's used properly versus improperly used, sagging down into the sleeping environment to help consumers understand proper use of the product.

JPMA and the CPSC and others have also recommended against the use of a pillow-like bumper. So it's a very thick, thick bumper that looks almost like a cushion that you would put on your couch or a throw pillow you would put on your couch. That's something that we recommend against.

And the ASTM standard organizations is looking into a test at this time to evaluate with a product to eliminate those thick, thick bumpers that have been identified as a risk from the marketplace.

So these are a few examples of some of the current standards development.

To give you some background on how we got to work with Exponent, the JPMA in an effort to address the information on safety for bumper pads commissioned a study from an organization called Innovative Science

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Solutions.

In 2010, they came back with their complete, thorough review published scientific data which essentially they concluded that there is no current evidence that's supporting the causal relationship between crib bumpers and infant deaths. And its complete review is due to be published in peer review medical journal in the future.

But JPMA also felt it was important to have this study looked at and additional research done to provide some further data analysis and that's why we approached the Exponent group to assist us with this additional research.

And they're here today to present some of their findings. So at this time, I'd like to turn this over to Michael and Joe.

DR. SALA: Hello. My name is Joseph Sala. As I stated before, I'm with Exponent. Exponent is a scientific and engineering consulting firm.

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We often assist clients whether it be manufacturers, associations dealing with manufacturers in handling some of the technical issues that they might be dealing with and to evaluate certain evidence brought to them and to help them make key decisions often related to safety.

As far as my personal background goes, I hold a Doctorate from Johns Hopkins University in Maryland and I achieved that in cognitive neuroscience. From -- from there, I went to Stanford University to continue and -- continue my education through a post-doc or postdoctoral training.

Once at Stanford, I received a National Research Service Award through the Biopsychology Department and from there found Exponent. And I utilized my skills and knowledge and technical knowledge of what's known as human factors to assist in applied studies such as this.

While at Exponent, I have had a focus on

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child safety. I consider developmental abilities and limitations with children, how both children and parental attitudes and behaviors affect safety across a wide variety of environments.

And I also routinely analyze and look at the databases on injury and fatalities that are maintained through the national organizations like the Consumer Product Safety Commission.

DR. PRANGE: My name is Michael Prange. I am engineer. I got -- I have a Ph.D. in Bioengineering from the University of Pennsylvania. I continued my education and my work at Duke University.

I have a focus on pediatric biomechanics. And just to give a background, biomechanics is in essence the application of mechanics to the human body, how we respond to forces, how we move according to forces.

And so my focus has been on pediatrics specifically, the unique aspects of children as

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compared to adults, size, shape, property, that kind of thing. And that's often led me to working on projects on injury causation and any intervention.

DR. SALA: I'd like to just begin the discussion on some of the work that we undertook and the results that we found from this by referencing back to what Lauren really described to you as our task in this matter.

We were contacted to review the literature and the evidence out there in the -- in the community as to whether or not crib bumpers pose a significant risk or a serious risk of injury or fatality to the -- to infants and the sleeping environment.

Now, in doing so, we -- we reviewed impending research articles as well as the research that Lauren mentioned by ISS, Innovative Science Solutions.

And the message across both the study that ISS performed for the Juvenile Products Manufacturers

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Association and across the scientific community at large is really quite consistent.

Routinely and consistently across these studies, there is an absence of any evidence that crib bumpers pose a significant risk to the sleeping environment or within the sleeping environment.

The Consumer Product Safety Commission produces an annual report on the sleep environment and sleeping child safety and at no point has crib bumpers ever been the focus or an item which has been called out to pose a risk.

Additionally, in 2010, there was a -- an additional study and a White Paper that was produced subsequent to it by Dr. Nakamura. And this article clearly addresses crib bumpers and evaluates the evidence seen within their own data, CPSC's own data as to whether or not they pose a risk to infants. And based on their own analysis, CPSC fails to find that the crib bumper poses a risk to sleeping infants.

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Additionally, as Lauren mentioned, ISS reviewed epidemiological data both within -- that has been produced both within the United States but also internationally and, again, consistently never has crib bumpers been raised as a factor related to SIDS or to infant fatalities in the sleeping environment.

Indeed, a specific study design was designed to address this issue and consider crib bumpers as an independent factor and failed to find any evidence that they posed a risk.

Now, as Lauren mentioned, there is controversy. There has been a -- an article, and I believe that this was provided to you originally, that -- that addressed the issue of crib bumpers being associated with or causal to -- to infant fatalities.

And we reviewed that data as -- as Bob mentioned. We attempted to obtain the underlying data itself. Unfortunately, that data was not available. And we through the evaluation of the same databases

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were able to collect that data and verify based on information provided in the report that we were dealing with the same underlying data or to a large extent the same underlying data.

Our re-analysis of that data and consideration of not just what was provided in the report but the underlying in-depth investigations and supporting materials that were obtained by -- from the Consumer Product Safety Commission when looked at and considered is very much in line with what the existing scientific literature says about the sleeping environment and infant fatalities.

Largely the inclusion of adult bedding or additional items such as pillows, comforters, stuffed animals pose the most significant risk to the sleeping environment.

Included in the report that we produced are photos taken from some of these in-depth investigations that show what some of the crib

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environments associated with these fatalities looked like.

And if you look at these, you can see clearly that there are a number of products, there are a number of items in that crib that would certainly be identified by anyone looking into these matters as significant risks to child safety.

And now, yes, it is -- it is as presented by Bob and as -- as is cited in the Journal of Pediatrics' study, it's quite easy to see how a parent may want to put these soft items in with their child to make for a cozier or a more plush sleeping environment, but it is, in fact, those items, those comforters, those pillows, those stuffed animals that would pose a significant risk to the sleeping child.

DR. PRANGE: So as part -- also as part of our study, we certainly wanted to look at the potential for bumpers to prevent injuries in this environment. And we looked at again the literature at

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large.

Basically in December of 2010, the CPSC has a final rule on crib standards and they identified the accidentals that are occurring in cribs. Certainly the most common one is falling out of a crib. But after that, the most common injuries are limbs getting caught between the crib slats, falling inside the crib and hitting the crib structure, and getting stuck in gaps, pretty much structural failures. These are -- these are identified as the accidental injuries that are occurring out there.

In their more recent paper in 2011, slide E, which I think you guys had as well, they also identified after falling out of a crib, the most common accidental injuries are getting limbs caught in between slats and falling inside the crib.

We also looked at that similar data, made similar conclusions. If you look in more depth at that data, you actually can see that out of the

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incidences that -- that occurred were limbs, arms, and legs are caught in between the slats. You know, approximately about 50 percent of those end up resulting in some kind of fracture and/or dislocation. So those are the kind of injuries that are occurring out there.

And the -- and the falling inside of the crib or -- you have, you know, the head and face are the vast majority of the location of those injured and, you know, 20 percent of those are listed as either fractures or internal injuries which most of those were closed-head injuries.

So I think, you know, these are certainly, you know, for a crib bumper too many of these injuries, it's going to be determined by a multitude of factors, you know, the specifics of the crib or with the bumper, characteristics of the padding, where it's located, how big it is, the age of the child, all these things that could. But I think the point is,

you know, these are injuries that actually could be actually prevented by a bumper pad.

And just to note, these are injuries that are actually reported in the emergency room. So these are actually parents taking their children to the emergency room to get them evaluated for these injuries.

MR. LOCKER: Yeah. So let's talk about JPMA as well in terms of education involved in this issue. This has not been a new issue. JPMA was intricately involved with the CPCS and the Clinton Administration in developing our nap time to nighttime program, which is what you have here, focused both on crib safety and also infant bedding safety.

What consistently comes through as has been explained by Bob and Michael is that the -- there's been a lot of the confusion about the issue and the profiles of what the hazards are and where they're presented from.

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There's often been a rush to judgment to impute all products to be of the same nature which is to say it becomes oxymoronic almost to say all soft bedding is hazardous when that is not really the case. But the case is that the use of pillow-like products that is by far presenting the greatest amount of problems.

Hence our focus on the nap time to nighttime education by partnering with the CPSC, the National (indiscernible) Health and Child Development and also the (indiscernible) at the time, impact of sleep initiatives, impact of sleep campaign.

One thing missing from the data set and this debate is that important distinction. The other thing that's in the analysis that's being discussed here tonight, and I'm actually going to repeat, is the public on this issue has been this significant distinction between the types of products that are involved, and I think Joe and Michael touched upon it.

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Primarily the vast majority of products associated with infant mortalities have been (indiscernible) placed in infant sleep environment or taking the infant and not even having a crib, basinet, or playpen that's a suitable sleep environment for the child and placing him in other hazardous situations to the point where it's become an epidemic.

The city of Milwaukee, their public health commission recognized that's an epidemic health problem.

There's been enormous amounts of deaths associated with unsafe sleep practices where children are placed in either a hazardous environment that doesn't even involve a crib or when placed in a sleep environment infused with a lot of this bedding which is very -- also evidentiary of the points raised about the concern about the unintended consequence of not having products that are specifically designed to create a safe sleep environment available to the

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public.

The -- this was also duplicated even recently by the Children's Memorial Hospital in Chicago. In their study, they estimated that 90 infants a year die in an unsafe sleep environment because of a failure of adequate cribs and other safe sleep environments being made available to them, primarily in the African American community.

So there is a lot of evidence out there. CPSC's own analysis as they're moving ahead with the crib rule making, which at this point goes back to new crib standards, which we were very involved in developing, as of June 28th of this year also noted that there was a significant point, as Michael noted, about injuries associated with the adult bedding and that these injuries, that there is a utility to these products because the injuries that they see apart from the -- the number two highest significant injury to children in a crib occurs from limb entrapment or the

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body against the hard surfaces of the crib.

After children climbing and falling out of the crib, the highest percentage of 22 percent is related to that. And as of March 11th from the CPSC's own public database on line, they've seen even a higher percentage rate. That seems to be the complaint.

Of those, as Michael did point out, a lot of those, a high percentage, 12 percent all of these incidents resulted in emergency room treatments. So it's a fairly high percentage.

Part of it is because of the very nature of the standards in place, the crib standards developed by the federal government. The slats that are the national requirement of the cribs are so narrow and tiny because it was designed to protect against the 90 -- the fifth percentile infant without a diaper moving backwards feet first through an opening and having their head caught.

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And as recently as two weeks ago, you see that type of scenario, but they didn't allow for the diapers. So as a result, you have those narrow spacings. There's nothing we can do about it. That's mandated by federal law and the reevaluation of the Commission was to elect to maintain that slat spacing and not change it to allow for diapers.

Hence the problem of these types of limb entrapments, fractures, bruises that occur in the crib. So improperly designed products that are not pillow like, and that's a term you've often used to describe it, can provide both benefit and (indiscernible).

And finally we believe a significant or the unintended consequences that were seen in these high fatality rates associated with cities like Chicago, Milwaukee, and we think it's emblematic across the country and (indiscernible) involved in Sudden Infant Death Syndrome and to try to prevent these types of

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deaths.

So this is distinct from those products. If we can -- even in the sleep position, it became obviated as children were placed to sleep and (indiscernible).

DR. BEILENSON: (Indiscernible.)

MR. LOCKER: I think we can stipulate that bedding, adult bedding --

DR. SMITH: You can't hear -- you can't hear him?

DR. SMITH: We can't hear it. We can't hear you.

MR. LOCKER: I think we can stipulate that just looking at adult bedding is (indiscernible). So in the crib, we -- when we say bed --

DR. BEILENSON: So I have one single question. Dr. Sala talked about the absence of any evidence that crib bumpers are a risk to infants and Ms. Pfeiffer talked about the ASTM standards that

explicitly talk about type of tie and not having a sagging bumper. And if you talk to other people, human behavior and wanting to have these things.

So if these are not dangerous and if you cannot expect parents to perfectly follow the guidelines, why are we having these problems?

MS. PFEIFFER: Why do they have the ASTM standard?

DR. BEILENSON: Uh-huh. Why does ASTM standard say type of tie and not have sagging if indeed these are not dangerous things?

DR. SALA: Well, if I -- if I may address that. I believe that this gets to the -- one of the points that Rick was making is that one product -- we like to talk about the crib bumpers in general, but it's not to say that, you know, our knowledge and that we shouldn't apply our knowledge of what we know of safe sleep environments.

I think that just as you might see in some

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of those photos, there are loose blankets in the crib and that could be a hazard.

If a product was, like even a crib bumper, was just placed in the crib unrestrained, it would be very similar to some other sort of bedding product, but that's not the use of this product. The use of this product is prescribed by the instructions and by the purpose of this which is to lie it against the slats and to be tied in a specific manner.

Now, the -- I think the efforts of the ASTM are to make sure that the product is presented to the consumers in a way that it is able -- most accessible to them to be used in the proper way and not to be misused or used in an unintended fashion to the detriment of overall safety.

MR. LOCKER: I would add one thing in terms of that context. When you look at the complete issue, you have to look in terms of it's always good to have instructions for proper uses of products.

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And certainly we're not looking to create -- just like we have standards that deal with even -- what most people need to realize is the crib sheets themselves and the depth of the pocket and the amount of materials to avoid strangulations risk, we would have a requirement to deal with any cord length or string length for anything that goes in the children's sleep environment because we want to have products that are safe for use in that environment as opposed to products that are clearly unsafe in that environment.

We think the data itself is pretty compelling because we know that over a ten-year, 3.8 billion units sold in the marketplace of these items and that the CPSC has recently in an address to the chairman of the agency, and it's been about two months ago, did reconfirm, as the doctor, Dr. Nakamura, at the agency that there's no causal nature.

So measured against the converse result

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(indiscernible).

MR. ENTEN: I was going to say that I think they're taking the position that because a product comes with warnings means you can't buy any consumer product that doesn't have a warning on it some place. And I think if an industry tries to -- health officials to make sure to get the message out of proper use of all products including these products.

DR. CHENG: Can you review what product you're (indiscernible)? Does it mean it's been approved for bumper pads and with the evaluations about the effectiveness of these pads?

MR. LOCKER: We can talk about what we've done in terms of the standards of the environment. We did touch upon that. Certainly in terms of the length of the ties, the method of attachment, and the significant distinction between pillow-like products or products, taking a set of adult pillows sew them together and run it around the crib, products like

that and the traditional type of bumpers since they've been firmly and fairly secure on the side of the crib. Those are the focus and the standard. And also the public education and an effort between the association and other groups and the reason -- I mean, I wish we had better wording. We think the communication does need to be improved. We really think if we had better wording between this distinction between quote, unquote originally what was soft bedding which is a hazard and other bedding which isn't, this is sort of, like I said, oxymoronic (indiscernible), but everything is soft and when dealing with babies. But that seems to be the main aspect of it and we've developed this sort of pillow-like distinctions. We think as a practical matter since the last decade there's been a dramatic change in that because we worked hard to ensure those products are not on the marketplace and we do not favor those pillow-like products on the marketplace.

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But conversely we believe there is utility and value with the traditional bumpers that are used to keep babies safe.

DR. CHENG: So the ASTM standards are voluntary standards for people to implement?

MR. LOCKER: Well, right now they are. But as you may or may not be aware, Congress in 2008 passed the Consumer Product Safety Improvement Act, and they mandated at the rate of two for every six months, Consumer Product Safety to review thoroughly product standards and look at the federal regulations and make those mandatory as needed. That's what's going on. That's why you see the new crib standard and you'll see a new basinet standard and a new stroller standard and those are all in the pipeline coming down as new mandatory federal regulations. And the impact of those regulations will be that no one will be able to sell these or use the products.

DR. CHENG: So just clarify for me, the

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current standard for bumper pads is no --

MR. LOCKER: The association's position is that (indiscernible) and we don't -- we can't say.

DR. SHARFSTEIN: There's no ASTM standard on this?

MR. LOCKER: No. They're proposals right now.

DR. CHENG: Okay.

MR. LOCKER: There are standards on ties. And as a practical matter because of this process that occurred in the mid '90s, a mass segment of the market has been pretty well tested in terms of the types of products which is why something known as a (indiscernible) and the subset you see don't account for these substantial shifts that occurred a decade ago from, you know, from prone sleeping to supine sleeping as well as the marketplace changes that took place because most of the data sets that everyone is talking about are actually sets that are old, which is

why we looked at the CPSC's and part of the public record in the ruling. And they were looking at data subsets that were dated 2007, 2010.

Something that I know that both Joe and Michael did as well something was missing from those data sets.

DR. DAYAL: When the panel met last time, we agreed that the evidence surrounding, and as you all have reiterated, too, the evidence surrounding crib bumper has association with infantile death. It's obviously controversial and sometimes it gets reported and sometimes they don't.

So I'd like to ask a different question. Now, what data do we have of the crib bumpers that you have in there? Because when we look at the panel's decision last time it was that although there is a risk that we think of that we can't quantify, we were all struggling to answer the questions for what the benefits were. At least when I looked through your

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reports, the explanation, all the data you provided, I didn't see anything in support of that. And I'm sure you looked hard for that. I would, if I were in your position. So can we talk about that?

MR. ENTEN: Let me start out by saying I read the transcript several times and that's an obvious question. I mean, that's an obvious question that you all struggled with. So to pull down some terms. It's -- your decision was you felt there was no benefit, so why take a risk at all? No benefit. Don't take any risk.

But I think that there are people out there and maybe it's not a statistical scientific study -- I'm not aware of any statistical studies, scientific studies, but I think there are experts out there that believe that the unintended consequence of removal of bumper pads because of the public -- you all talked about this. Dr. Cheng mentioned it several times -- is that it's so embedded in the public psyche that

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bumper pads are protective. What is the public reaction going to be when you can no longer purchase a crib and bedding that has bumper pads?

So I think the benefit, my answer is that the benefit of bumper pads is that it has a negative impact. Parents would put something else in the crib which we know clearly and inapplicably will lead to serious injury.

The other thing I would point out, I guess, I think Rick mentioned it, and one of the people from Exponent mentioned it, is that the CPSC clearly states that there are high percentages, 22 percent of injuries caused by wooden slats in cribs and then 12 percent they have to end up going to the emergency room.

Now, there's no data that says, okay, well, let's remove those and see if those numbers go up and how are you going to study (indiscernible) infants in cribs without bumpers? There are no studies of what

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happens to an infant when he's put in a crib that doesn't have a bumper pad. Okay?

So how do you know who can say that there is no benefit because there's not been any study at all which says this is what happens. We're going to take a hundred infants and we're going to make sure that the parents agree not to put bumper pads in those cribs and see what happens to those kids. Nobody is going to do that.

So how would you have scientific evidence that would show what happens when you don't put a bumper pad in a crib? You could (indiscernible). Maybe you all as physicians you believe that bumper pads are dangerous and you didn't put them in your crib with your child or maybe you didn't have any injury as a result of that.

But how would you have that study? The only thing I know is that Kennedy Krieger, American Pediatric Association, Maryland Association of

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Pediatricians all believe that an unintended consequence of banning bumper pads could be an increase in juvenile (indiscernible). To me that is kind of the same as saying there is a benefit to having these pads in the crib. And until somebody can show what will happen through some study, they may never be able to show it. What happens if you remove them? I don't know that you can really ever nail an answer to that question down.

DR. BEILENSON: It's something to think about (indiscernible).

DR. DAYAL: Can I finish my question? That didn't answer my question. So just to be clear, we do not have scientific evidence that shows that crib bumpers, and the reason we don't have it, maybe a good we don't have it. But where we are today there is no scientific evidence that crib bumpers are beneficial to babies.

MR. LOCKER: I wouldn't say there's no

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evidence.

DR. DAYAL: There's no scientific evidence.

MR. LOCKER: I think there is scientific evidence because the CPSC has announced -- has identified the hard surface inside facing the crib has identified the hard surface of the cribs and the wood. And the slat spacing has a focal point of injury, the second highest point of injury.

And so also you would expect that any barrier that prevents entrapment would be a benefit, a benefit to the obvious potential to avoid such injuries. So we can expect to see those numbers, the 22 and 12 percent numbers, the second highest level of (indiscernible) with crib (indiscernible) to prevent with that.

And you can even go right on line now as we sit here and you'll see as of two weeks ago, one of the more egregious examples was a child falling feet first up to her neck in an improperly assembled crib

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without a barrier and it was almost a fatal consequence.

MS. PFEIFFER: I'd also like to add I recognized in the transcript that you also felt that consumers were using this product (indiscernible) the reasons they were (indiscernible) the interests of it as well to understand the uses of the product.

Being a mother and having a child myself, I hear things from other parents and I know that they said that they used that product. They never had a problem with it and they use it because they want -- they don't want their child to bump their heads.

Of course, that is anecdotal, but these are some of the things that you hear when I discuss this issue with other parents.

DR. WILEY: I actually have a new question based on Mr. Locker's statement which was how did the CPSC come to the conclusion that the slats were a risk with infants? What data did they use to determine

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that actually was the risk?

MR. LOCKER: Well, the original --

DR. WILEY: I mean, was it a debate? Was it a theoretical or was it a truly measured --

MR. LOCKER: I'll tell you how they originally came up with the requirements and how they've been measured the consequences of that which was based at the University of Michigan metric study, they adopted the original crib regulation (indiscernible) which has just been rescinded.

They measured the development of infants and their propensity to move backwards feet first through openings, and they took the example measurements and they developed a standard because they noticed that without a standardized dimensional requirement on cribs, there was an increased risk of head entrapment, the head being proportionately larger to the body. And then they got to the (indiscernible) in terms of the dimensional part. They didn't expect that the

natural outcome of perhaps not allowing the (indiscernible) would be this dramatic rise in limb entrapment and some injuries when they originally developed the crib standard in the early '70s. That became a natural outgrowth and they began to track with increasing frequency. And as a result, as they looked at all the injury data from (indiscernible) systems that their data would bring and they began to note increasingly that that injury criteria was a rising factor that didn't exist before that. Yes, you had less. You didn't have anything associated with head entrapment. You're going to have injuries associated with limb entrapment and other types of impact.

DR. WILEY: I don't think we're here to debate that part. I think that we have to be very careful running to that conclusion for a couple of reasons.

Number one is you're looking at emergency

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room data which means that you're now dependent upon the history given to you by families bringing their child in. And for those of us who are pediatricians, we have certainly come to understand and recognize that that may not be the most reliable source as opposed to (indiscernible) in which there are either police or even potentially knowledgeable investigators who were at the scene or making judgments.

So I think we have to be very careful about extrapolating from emergency room data. And I don't know the history of this, but let's suppose sometime after that regulation, an increased effort was made to measure that data from emergency rooms may have reported change, but we don't know any of that.

So I think it's very dangerous to make suppositions based on those kinds of evidence. I really do.

And I understand the issue about increased injuries, we don't know if the injury that you're

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seeing at the emergency room is directly related to what the story was of how the injury occurred.

Even if they saw a limb in a slat --

MR. LOCKER: And Joe can talk to you about that, but I don't want to be left with the State's impression that is (indiscernible). That issue was statistically valid in extrapolating the -

DR. WILEY: I understand. And I think probably most people even those of us who might be most cynical would still agree that a large number of reports suggest that there is a trend or a problem.

In other words, I would agree with you that based on this amount of data, especially presented by (indiscernible) to suggests that maybe there is an issue about increased nonfatal, maybe even moderately serious or non-serious injuries.

I'm sorry. Are you going to say something?

DR. SALA: I just wanted to comment on you. Certainly that is -- that's an issue that we deal with

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in these data reporting structures. And I completely agree that oftentimes the available information is from a narrative.

However, I would like also to point out that a lot of the underlying data related to the fatalities that we're dealing with also does come from (indiscernible) data source.

VOICE: (indiscernible)

DR. SALA: Oftentimes I think in think in these situations, you're dealing with events that have transpired. Obviously they are emotional. The parent often removes or alters in some way the death scene itself and there's a number of accounts in even the data that we have on these sorts of fatalities that show that even the parents' attempt to reconstruct or more in-depth investigations afterwards as to what the scene looked like doesn't comply with what the initial photos immediately taken afterward look like which probably also did not appropriately capture what the

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scene was at the time of the fatal incident.

So I think this is certainly an issue. However, I don't think it's solely an issue for the injury data. I think that it's pervasive and a part of some of the issues we see.

DR. WILEY: So here's my question and my question is this. (indiscernible) that you read the transcripts, you understand we struggle with the issue because there is clearly never going to be a really elegantly designed and reproducible study that demonstrates the true evidence for or against these products and a very usually low likelihood of that.

In other words, who's going to design a study to prove that without any bias or without any prejudice that the presence of crib bumpers or the absence of crib bumpers offers advantage or disadvantage?

I think we have to come to a conclusion that that study is probably impossible.

DR. SALA: I think that there are

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alternatives --

DR. WILEY: I understand.

DR. SALA: -- so the panel's difficulty with this is they're looking at what is the benefits of the crib bumper versus -- even if 80 percent or 90 percent of the attributable deaths (indiscernible) are due to crib bumpers. What if it's not zero? What if it's five percent or if it's ten percent? What if it's 50 percent? What is the benefit of the crib bumper that balances that? And that's where the panel is focused. And we have yet -- not yet seen any evidence or hear any evidence that convinces me strongly that there is a benefit of a crib bumper.

I mean, what universe does the law of physics allow a five month old to turn their head at the side of a crib and damage their head in such a way that the crib bumper could have at the time prevented that. I can't think of a universe in which that's true.

You're a biomedical engineer. Maybe you can

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help me understand how that's possible. But I don't see how the presence of a crib bumper eliminates that possibility either way or that the likelihood of that kind of injury is actually going to happen in the absence crib bumper.

DR. PRANGE: I think that's borne out in the data I believe I presented before that, you know, for example the type of head injury. The vast majority of them were classified as superficial type of injuries. And even -- I mean, the ones that are internal, the ones that are termed that were mostly closed head injuries, that's a generic term for an awful lot of different things and maybe just is a very conservative diagnosis in that regard.

But at the same time, these are all injuries that are going to the hospital. These are -- they're injuries that are not just dismissed and say they're fine. They're going to the hospital.

DR. WILEY: Agreed. But again, I can tell

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you from experience that pediatricians emergency rooms is be very careful about coming to the conclusion about what the reason is that they're in the emergency room. So my question is, how do we reconcile this difference, this concern that a non-significant and statistical, but absence of significance doesn't mean absence of effect. How do we reconcile -- how does this panel reconcile that risk that we can presuppose or even find in some pathology, coroner reports against what we see, if a lack of significant benefit?

DR. BEILENSON: In the interest of time, why don't you think about that? In fact, Secretary Sharfstein has question and then we'll go through one more time.

MR. LOCKER: I'll say that the zero risk isn't in anything. I understand we learned about the public health and public health policy. We have this debate on vaccination all the time. You're not going to achieve zero risk. You do have some legal barriers

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to meet as a basis for policies. Even though you like to achieve zero risk, there are other requirements.

DR. WILEY: And that becomes the risk versus benefit.

DR. SHARFSTEIN: Thanks. I appreciate the chance to jump in, the chance to talk. I've got some - a few kind of quick questions, actually. I've got a few quick questions about that I just want to understand.

Is there a recommended age of use for bumpers? I've been reading a bunch of stuff and I just want to get from you guys to be completely clear. What is it?

MS. PFEIFFER: Sure. At the time, the standard says the bumper should be removed when the child can pull up to a standing position.

DR. SHARFSTEIN: That's the current standard?

MS. PFEIFFER: That's the current voluntary standard.

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DR. SHARFSTEIN: When the child can pull up to a standing position. Okay.

MR. LOCKER: I understand where that came from and that could change because that changes with crib standard. And the depth of the mattress height to the height of the top rail as the new crib standards come into place. But the original concern was, and you saw it in the data, number one injury statistically, was really the falls. So our concern was the bumper itself not become a sort of stepping to being able to let the child climb out of the crib.

But bumpers, has the (indiscernible) requirements that was below (indiscernible) on the slat. That would have a, the cribs themselves had deeper pockets. That in and of itself is a contributing risk of a fall hazard which is what you're trying to --

DR. SHARFSTEIN: Okay. I just want to make sure I'm just completely clear on where things

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(indiscernible).

The data that you presented on injuries in the crib, you didn't know whether there were bumpers present or not did you, in that data?

DR. PRANGE: That is correct. There was no coding specifically to say --

DR. SHARFSTEIN: Right.

DR. PRANGE: -- whether it was or was not.

DR. SHARFSTEIN: Injury, the 12 percent, it's unclear whether there were bumpers or not. I just want to make sure I'm a hundred percent clear on that.

In terms of the number one cause for where the babies launch themselves out of the crib, if you've ever heard a thump in the middle of the night, you know, that you're worried about. Is there a concern that you have that the bumper could contribute to that in any way? Is that a reasonable concern to have or is it a help in that in some way or, you know, what is your position?

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MR. LOCKER: Let me put it this way.

Certainly you wouldn't want a large bumper to become a stepping stone to going out of the crib. With that being said, if you look at the CPSC's fatality data related to falls in cribs, that's not been in evidence. No, those crib bumpers are not a causal factor in children falling out of cribs and suffering injuries.

DR. SHARFSTEIN: Has that been analyzed, that question?

MR. LOCKER: You can see it in terms of their fatality data which they do analyze and that led to these, but they did have that causal connection. They would have it.

DR. SHARFSTEIN: Well, but --

MR. LOCKER: For example, a (indiscernible), they found (indiscernible) a significant cause of death was falling on to other objects out of the adult bed and onto, by the bed and actually hitting something, not the floor itself, but something else.

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DR. SHARFSTEIN: Understanding your point and what you said, but this sort of relates to my other question. The CPSC hasn't analyzed the question of whether this is a contributing factor for falls? They certainly haven't stated it is a contributing factor for falls, but that's not something -

MR. LOCKER: (indiscernible) based upon almost every fatality certainly involving children that they become aware of, and we did know is that it's complete absence of data that bumpers is an issue as a contributing factor.

DR. SHARFSTEIN: Pillows? Is there a, what standard do you use or what's out there to decide whether it's pillow like or not? Is there any kind of standard?

MR. LOCKER: That's a communications issue. We say if it's, you know, like an adult pillow don't put it in the crib and we say they should be designed for cribs. And we try to avoid any doubt that it be

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placed in any sleeping environment, not just cribs.

DR. SHARFSTEIN: There are actually bumpers that are adult pillows with ties that go around.

MR. LOCKER: There used to be.

DR. SHARFSTEIN: But you don't know of any on the market right now or --

MR. LOCKER: There may be some, but I can't -

-

DR. SHARFSTEIN: And you would look at the dimensions of an adult pillow for that?

MS. PFEIFFER: Right. So some of the ASTM subcommittee is looking at right now this specific issue to try to determine potential test methods that would help to eliminate that type of product so they don't have to ask a specific time, a specific amount which has not been decided yet.

But they're working on that to try and make sure that the industry has a standard to follow so they know it's not a very thick product.

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MR. LOCKER: And in terms of the issue of that standard is voluntary. You should be aware that retailers that account for 90 percent of the product distributed in the United States are required to perform to the ASTM standards.

DR. SHARFSTEIN: Which ASTM standards?

MR. LOCKER: Retailers account for 80, 90 percent of the products distributed for sale in the United States require products meet the ASTM standard.

DR. SHARFSTEIN: Right. In this case, there's not yet a standard, but --

MR. LOCKER: In this case, there's not yet such a standard. But because the experience that occurred in the middle to late '90s, there was a wholesale sort of elimination for the marketplace of those more egregious pillow-like products.

DR. SHARFSTEIN: One other question I have. In the CPSC report, there's a number of cases where the child was found with the head smooshed up against the

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bumper. And I guess my question is, I understand the position that that is not proof that the child's death was caused by the bumper. I understand that. But there may be other things in the crib.

But I guess the question I have is, do you believe that it's possible that a child could given the (indiscernible) mechanism and air circulation and that whole spectrum, that it could prove dangerous through youth as a directive a child is smooshed over against the bumper given, you know, that this is the paper you distributed their faces struck by bumper pad (indiscernible) bumper pad, face pressed against bumper pad. Do you think it's possible that used as directed that a bumper pad could contribute to a child's death?

DR. SALA: I think that based on the CPSC's data and the underlying investigations that those narratives that you're reading from don't actually correctly or accurately reflect the full environment at the time.

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And so I don't know of any clear evidence from those reports that that situation has actually occurred. And many of these, there are ones that have a briefer narrative in a case against bumper pads.

But when you look at the investigation, there are instances where it's been noted that the mattress was a make-shift mattress that actually was a comforter wrapped in a sheet.

DR. SHARFSTEIN: Right. I totally understand.

DR. SALA: And it's very difficult in that situation to look at an environment like that and try to say whether in the absence of the make-shift mattress or a broken crib or space that opened up through some way due to a crib malfunction or a defect in the hardware of the crib. Whether or not the position that the child assumed relative to the other items in the crib would have related to the fatality.

DR. SHARFSTEIN: I'm not asking, though,

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about -- I understand that the evaluation is that there are other explanations, but I'm wondering whether this is a possible contributor in your mind, a mechanism.

MR. LOCKER: I can tell you from reports that went to the ASTM Committee, that they received that. That since the (indiscernible) opine sleeping, that we honestly have not seen that as a causal factor in fatalities in children.

DR. SHARFSTEIN: As it being what?

MR. LOCKER: As opined, a resting child against solely a bumper pad as having that as a cause of a fatality or suffocation.

DR. SHARFSTEIN: You're saying that they haven't found that to be the cause?

MR. LOCKER: Of all the data that's reported, we see this annually in the committee, we have not seen that to be a cause of death of an infant which is why I think you saw this arm of the CPSC two months ago basically said that.

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DR. BEILENSON: (indiscernible)

DR. SHARFSTEIN: I think a whole lot, but I think we'll leave it there. I just wanted to see if you have a quick cite.

DR. ARONICA-POLLAK: No. I think with deaths in these cases, I don't think that we can pull out what we want to pull out and say that, one, that can cause death. There are many contributors. One of them is the crib bumper. You're going to have a child who goes prone and goes up against the crib bumper. Children can roll and they can roll up against the crib bumper and they become prone. Sometimes they're placed on their bellies and sometimes they can roll and not get back over. So you're going to have now a prone child.

So when you now say, well, these are all prone, we have to throw those out because they're prone. I don't know how you can do that. These are multifactorial cases and I don't know how you can now say, well, you can't just blame a crib bumper because

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you also have a prone child and throw out cases.

MR. LOCKER: I'll let Mike because he looked at that, but I'm not saying that that's (indiscernible). But you do -- when you did have the data with a prone sleeping infant, it was primarily a result of being placed in the natural face down, not -- the fact that there is a bumper is just related to the -- it's not because of they're connected to it. They're usually placed face down on, let's say, a mattress or adult bedding. And so to say that there are incidents where the bumpers themselves caused the fatality is not the case or that it even contributed to it. It might have been there, but it's no different than saying that your (indiscernible), you know, to an accident versus causing that.

DR. ARONICA-POLLAK: I agree that there are certain children who die in the prone position and they're nowhere near the bumper. I absolutely agree with you in that case. But there are also children who

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die up against a bumper and they have morbidity patterns now on their face where they show morbidity where they are pressed up into it.

MR. LOCKER: For the data I can turn to.

DR. SHARFSTEIN: That's sort of a little bit of a restatement of my question which is, is it -- you know, do you think that it's possible that it could be a contributor to a particular child even if it's installed correctly based on the known -- you know, the findings in some cases understanding that in any one case, you cannot say that it was -- this was the cause?

MR. LOCKER: Pillow-like or traditional?

DR. SHARFSTEIN: The traditional.

DR. SALA: I think that that difficulty is as after looking at all this data and looking at all the evidence there, you know, as a scientist, you know, I - - we can't disprove or we can't prove anything.

And so you asked me if there is the possibility. As the scientist, there's no way to

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answer that in, you know, in an affirmative that there's no possibility.

But when I evaluate the evidence, beneath it there certainly isn't based on what's available and based on the patterns of what is -- what I observe, there is not sufficient evidence there to say that the crib bumper plays that contributory role in these events.

I mean, the underlying data that I have had in front of me and I received from the CPSC and considered with respect to what's been published, the - - it's not simply a there was prone sleeping position. We throw that out.

There were significant concerns in these underlying reports that maybe it's impossible to tease out and attribute that crib bumper as a role. And that's what as a scientist I have to --

DR. SHARFSTEIN: I appreciate that. Okay.
Peter, back to you.

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DR. BEILENSON: (indiscernible) occur from in cribs are zero to six months of age. I would think that I agree with Mr. Enten that the big crux of the final decision that we make was if there are no methods, no proved methods to bumpers and there's at least some risk. We came to the strong conclusion if there are no benefits and there is some risk, we can't quantify the risk.

I'm not trying to put words in your mouth at all, but we have not heard today in my opinion why bumpers are -- protect infants. I think I must have this wrong, but you said 22 percent of head injuries in cribs, from falls from cribs. So that results in fractures are closed-head injuries.

DR. PRANGE: Correct.

DR. BEILENSON: So my question is -- I know Dr. Wiley was sort of touching on this before. I've had five kids, a three month old. I don't see how a three-month-old can generate enough force to cause a

fracture with or without a bumper on a crib slat. Can it be accomplished?

DR. PRANGE: No. I mean, I think you're right. I mean, and that's why I said the data is sparse. And I even think that 20 percent probably is conservative in regard of, is closed-head injury diagnosis. That is probably a catch all, versus a general diagnosis and probably not representative of an actual serious head injury.

I think from our perspective that is not, you know, a number I can point to that would say a three-month-old could generate the forces necessary to do that. I mean, certainly a laceration or a bruise. Certainly that kind of thing, sure. It's more the -- it's probably the bigger accident that's more in play.

DR. BEILENSEN: And again just to be clear, our understanding from bumpers prevent that entrapment.

DR. PRANGE: I think logically from an injury point of view, if you put something in front of the

slat, you can't get your head through that.

DR. BEILENSON: I know that the bumper pad does not attach to the mattress. It certainly does slide up even if you tie it correctly.

DR. PRANGE: I think products vary, so it's hard to make a generality of this is how a product is. Certainly during my presentation, that's going to depend on the characteristic of that. Some of them are designed a little differently. Some of them are tighter than other ones. And so that will play into it, but certainly I can see a design of a bumper that would prevent a infant from falling out.

DR. BEILENSON: Do you have any questions?

DR. DAYAL: Yeah, two questions.

Mr. Locker mentioned that since the mid '90s or in the last decade that there's been changes in understanding adult pillow sizes and bumper pads.

Has the GPA -- do you have any guidelines around bumper manufacturing?

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MR. LOCKER: Yes. I think if you get the ASTM standards, you'll see what those are again if you look at the nap time to nighttime. I think the (indiscernible) we also urge people to adhere to that. And we ask members of our association to make a commitment to the requirement.

DR. DAYAL: Is that a voluntary?

MR. LOCKER: Right now that is --

DR. DAYAL: So potentially there are bumpers out there that are fluffy and but we deem unsafe.

MR. LOCKER: Our position is you shouldn't have --

DR. DAYAL: I'm not asking if you should. I'm asking is it possible that there's bumpers --

MR. LOCKER: There's always that possibility.

DR. DAYAL: So apart from the guidelines that you have asked people to comply with, there's really no outright standards, I guess, for lack of better words. So if I wanted to go on my own and manufacture -

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MR. LOCKER: No. We would not object to a standard that would say that you could -- your bumper pad has to meet certain requirements.

DR. DAYAL: And why haven't we done that because we're all in agreement on thing, that soft, fluffy adult-like pillows can lead to death in children, death in infants that we agreed to.

MR. LOCKER: I think it's underway right now with the ASTM Committee and process, particularly in regard to what government represents.

DR. DAYAL: That's fair, but you actually said these have been accepted since the '90s. So I'll say 15 years.

MR. LOCKER: What happened was historically as a practical matter what we saw when this first issue first developed is that those people that were making those products couldn't sell them in the marketplace anymore. So they sort of evaporated, eliminated from the marketplace. So we believe that they've been

largely eliminated from the marketplace.

And our concern now and the reasons we wanted it for the standard is we don't want new players coming into the marketplace who weren't around at that time that don't know the exact requirements and criteria and the standards that they should meet.

So we want to make sure that if anyone comes into it further, we would propose that actually be adopted as a requirement and regulation.

DR. DAYAL: But there hasn't been any.

MR. LOCKER: No.

DR. DAYAL: My second question is, and you referenced the, I can't think of the person's name from Kennedy Krieger who's written a letter to support the use of crib bumpers. But we also have several letters that say the opposite, one from (indiscernible), I may be mispronouncing your name, the professor from Johns Hopkins, a professor from University of Maryland who has said the exact opposite. And then we also have

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documentation from I think the Canadian Pediatric Society saying that crib bumpers shouldn't be sold.

My question is, these people know best the manufacturing of crib bumpers. Why do you suppose that they're clearly strongly recommending that crib bumpers not be used?

MR. ENTEN: I think honestly people have different experiences, different views. As we said, there's not a tremendous -- as you said about scientific data, when you stop, people have feelings about it.

I for one I think the gentleman from Hopkins was in the School of Public Health. The person that, Dr. Levy is from Kennedy Krieger. I do know that the American -- the Maryland chapter of the American Academy of Pediatricians did not feel that bumper pads at this time that the evidence was there to justify a complete ban.

And we talked about the lack of benefit of

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(indiscernible), what I said in my opening statement, that the, while it's anecdotal, that pediatricians -- there are a significant number of pediatricians who apparently believe that the benefit of bumper pads is that we don't have -- you will not see the unintended consequence of an increase in clearly dangerous bedding in the crib.

And you have to weigh do you want to take that risk? We may have a situation where at some point in time, we see a spike in serious injury fatalities because bumper pads have been banned.

DR. DAYAL: But unintended consequences can go both ways. You could also -- I could just as well argue the fact that we're putting bumpers in leads you to believe that putting kids, putting things into bumpers in is a safe thing to do. And by not having bumpers, you can reinforce the message that nothing should be placed. Unintended consequence of itself, by definition, is unintended. We don't know that. So now

we're going into the land of hypotheticals.

MR. ENTEN: Let me just say this. From your transcript, a lot of discussion about education and outreach and that's what we're doing in other cities, Milwaukee. A lot of people are working very hard on that.

And, you know, when I read the transcript, there's one part of the transcript that says, oh, education is not enough. But then when you have the discussion about the unintended consequences it says, well, we can educate people on that.

I think we believe we need more with education, you need more with outreach, and that we shouldn't take a leap that no one else has taken, because, you know, there are experts out there that believe that this will have, plus the possibility of the negative unintended consequences.

DR. SHARFSTEIN: I'm glad we got the transcript made. Somebody has dog-eared the

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transcript, so I appreciate it.

DR. PRANGE: I wanted to add to your, you know -- I can't comment on why these people think the way they do obviously. So I can look at the scientific literature. That's kind of what I have of my basis.

And really the evidence that's purported of the risk of these bumpers comes back to that one paper in 2007. It comes back to that's really the only paper that has -- and I think you've seen our report and you read it. There's a lot of methodological and interpretive laws and that people -- if you read it on the surface, you don't see them.

That seems to be the one focus and that's why, you we kind of took this study to really understand the data. And I think we pointed out that it's really -- the conclusions in there were not really valid to make given --

DR. BEILENSEN: That's -- well, I want to thank the panel for coming. You can certainly stay.

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We're going to have our discussion. Do you have --

DR. SHARFSTEIN: I just wanted to thank you first for coming and for, you know, from various distances to be here, for reaching out to us knowing that we're looking at the -- and we're also engaging in some pretty serious back and forth with us and with the panel members. So, you know, this is all, you know, extra work for you guys on top of your usual jobs. So I --

MR. LOCKER: It's our pleasure. And if you were to call us, we would come.

DR. SHARFSTEIN: It may be that there is follow-up in the department on some of the specifics and we'll follow-up.

So I think maybe, Peter, are you going to steer everybody to the last part of the meeting at this point?

DR. BEILENSEN: (indiscernible)

DR. SHARFSTEIN: Okay. That's good. Do you

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want to take like a one minute break or anything before you convene? No? You're okay?

DR. BEILENSON: (indiscernible)

DR. SHARFSTEIN: What's that?

DR. BEILENSON: This is public, right?

DR. SHARFSTEIN: This is public. Everyone can stay. But we'll turn this over to you all.

DR. BEILENSON: I think we don't have to go in 20 some questions that we did before. The issues whether you heard today changes what we were doing before. So I'll open it up for comment.

DR. CHENG: I guess I have one comment and that is I think we can argue about what happens to these children that die and we're never going to know. And what we essentially have is a large case which as we know is causality is not strong.

I think that we should push for having a case control study done, a CPSC study when they do the investigations to see if there is a good number or not.

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And we can do (indiscernible) and try to understand this from the perspective of what crib bumpers contribute to the death of a child, but also potentially if there are injuries from entrapments or other falling out of cribs. I could add the crib bumper.

I know that they have ties, but as for -- there's a crib bumper there would help us (indiscernible). So I don't know if that's a recommendation that we can make to the CPSC, but that question.

DR. BEILENSEN: Which is decision that we made.

DR. CHENG: I think one of the questions was what should we recommend for the CPSC.

DR. BEILENSEN: We could recommend that there's nothing (indiscernible) that was mutually exclusive. We can still recommend (indiscernible) and the CPSC.

DR. DAYAL: My comments are I don't know if my position -- I don't think my position has changed since we last met because again we're using scientific evidence, one convenient, but one inconvenient, or there is a lack of it.

So I do agree with the comments made that there is the evidence around crib bumper like we talked about last time and sort of with crib bumpers is not big enough. On the other hand, nothing today has convinced me that there is a benefit for crib bumpers.

So this is exactly where we left off on May 20th. We think there is some finite risk and we are unclear if there is any benefit.

DR. BEILENSEN: One quick comment because the benefit that was referred to by Mr. Enten was the potential unintended consequence and the lack of change (indiscernible). People did not really want to have this.

But I would argue that the (indiscernible)

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sleep and the fact that the kids now sleep on their backs shows that, in fact, parents across the social economic span can learn, can pick up these things.

So we always talk about -- I know the education (indiscernible) in a really strong way, as Dr. Sharfstein believes, there would be a way to obviate that.

DR. WILEY: My thinking about this has not changed dramatically, although my struggle with it has increased. I think that we've heard very good arguments about why a group who's a strong proponent of crib bumpers for economic and business reasons actually make good arguments.

But, again, we stated before and I'll say it again, absence of evidence does not mean the absence of fact. And the absence of (indiscernible) risk does not mean the absence of true risk. And we I think are relegated back to looking at what evidence has been published and what theoretically and what makes sense.

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And I still struggle with that issue of I am trying to find a true viable benefit by which a crib bumper protects an infant from a significant injury that outweighs the (indiscernible) opportunity for a crib bumper used appropriately or inappropriately and a child placed supine or prone appropriately or inappropriately puts them at risk.

And it's still a struggle for me, but I still can't find the benefit substantial enough to outweigh the risk.

DR. BEILENSEN: Should we recognize Ms. Pollak. What were your thoughts on this as we move the discussion? What have you seen in Maryland whether they've been related to ties specifically or are they always, as you're saying, supine or prone with the face against the --

DR. PRANGE: I can think of one that we have attributed to the bumper was prone.

DR. BEILENSEN: And how did you attribute it?

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DR. PRANGE: The child was found with his face in the bumper. I would say the crib was at an angle. The head of the bed was upward. So the caretakers were doing that for acid reflux. So when the child is found, it was down on the corner.

There were other things in the crib. However, I, the one who did this case and spoke to the caretaker myself, those things were not around the child at the time. There was -- it was clear that this was a morbidity pattern that --

VOICE: It died in that location?

DR. PRANGE: Yes. This was clear that this occurred. So whether or not this was an issue more so than anything else -

DR. BEILENSEN: How old was the baby?

DR. PRANGE: Four months.

DR. BEILENSEN: What about, what other literature have you seen on this issue?

DR. PRANGE: Again, most of the literature,

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the article that you read. My interpretation, though, of the article again all of these deaths that were seen are multi faceted. I don't think you can tease out one or the other when there's blankets involved, when there's a bumper involved. This was a bumper as well. This was not a thin bumper. This was a thick one.

DR. BEILENSON: The one you talked about?

DR. PRANGE: In my case, it was thick. I don't think you can tease it all out. But I do think that when you see it and you know that it's there, it's one of the contributing factors.

DR. BEILENSON: What do you guys recommend to your patients, using bumpers or not?

DR. PRANGE: No.

DR. CHENG: So, I mean, I was one of the advocates of education and I would still very much advocate education because of the consequences and because I think this whole issue and the (indiscernible) requires a lot of education. I think

that I was the one who was saying on the actual that I would continue to abstain on that because of the issue around that evidence and the potential. But I think there should be major efforts made to (indiscernible) and to educate.

DR. BEILENSEN: So, Marsha, I think they're having problems hearing us.

DR. SMITH: Yeah. If you lean forward and make sure you speak into the, --

DR. BEILENSEN: It sounds like we kind of came to a similar consensus. Three of us agreeing --

DR. SHARFSTEIN: Peter, before -- could I just clarify one thing with Dr. Cheng?

When you say education, what is the message that you're supporting?

DR. CHENG: I -- so I think it kind of depends on what the decision would be. If the decision is getting rid of bumper pads, I mean, in general, I don't suggest not using bumper pads to my patients, but

if the decision is not, in response to -- I mean, it's the same ABC.

DR. SHARFSTEIN: But education is, in part, do not use bumper pads, you're thinking, but the evidence isn't there for regulatory, as we're hearing, regulatory action. But given the evidence and the situation, you would be supportive of education around not using bumper pads?

DR. CHENG: (indiscernible). And if there is regulation that says we don't have bumper pads, I think even more vigorous in education.

DR. SHARFSTEIN: Thank you. I just wanted to clarify.

DR. BEILENSON: Do you have anything?

DR. SHARFSTEIN: No. I just wanted to be just clear on what Dr. Cheng was referring to. So please proceed. I apologize.

DR. BEILENSON: Do you -- you don't (indiscernible)?

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DR. SHARFSTEIN: No. You don't need to take a vote. I think everybody was pretty clear on their thinking. This is challenging topic. I think nothing else from our side, are we done here?

DR. BEILENSON: We are done then.

DR. SHARFSTEIN: Great. Thank you.

MR. ENTEN: I just want to if I could state,

--

DR. SMITH: Are we, are we adjourning?

DR. BEILENSON: Based on the transcript and we discuss anything legalities whether this can be done by regulation or not. That's why I haven't raised that issue today.

DR. SHARFSTEIN: Correct. I totally understand.

DR. SMITH: Thank you.

(Whereupon, at 3:46 p.m., the above-entitled conference was concluded.)

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